

DEC 19 2003

10. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is being submitted in accordance with the requirements of The Safety Medical Device Act of 1990 and 21 CFR Part 807.92

510(k) Number K032251

Date of Summary

Preparation: July 10, 2003

Submitter: ImmuneTech Corporation

Contact Person: Vivianne Noetzel

Address: P.O. Box 9433
17394 Via Del Bravo
Rancho Santa Fe, CA 92067

Phone: 858-756-8483

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Manufacturing Site: ImmuneTech Corporation

Address: 888 Oak Grove Ave., Suite 4
Menlo Park, CA 94025

Phone: 650-470-7420

FAX: 650-470-7423

Device Trade Name: ImmuneTech™ Total IgE System

Device Common Name: Total IgE Test System for the measurement of total IgE.

Device Classification: Class II (21 CFR 866.5750)

Device Product Code: 82 DHB

Performance Standards: None established (as a medical device) under Section 514.

Device Description: ImmuneTech™ Total IgE System is a test for the measurement of total IgE in human serum. The ImmuneTech™ Total IgE System consists of two components.

1. Flow Cytometer instrument with software for ImmuneTech™ Total IgE System
2. ImmuneTech™ Total IgE System Reagents

A serum sample is mixed with anti-IgE coupled microspheres. If present, IgE in the sample will bind with the microspheres and form an anti-human IgE / IgE complex. This complex is then sequentially incubated with biotin-labeled-anti-human IgE antibody and fluorescent-labeled-streptavidin. If IgE is present in the sample, the final sandwich complex of anti-human IgE / IgE / biotin-anti IgE / fluorescent-streptavidin will form. Measurement of the fluorescent signal from the sandwich complex is directly proportional to the concentration of total IgE in the sample. The flow cytometer with ImmuneTech™ Total IgE System specific software will measure total IgE concentrations.

Intended Use: The ImmuneTech™ Total IgE System is a quantitative *in vitro* diagnostic test system that measures total IgE in human serum. The ImmuneTech™ Total IgE System is intended for clinical laboratory use. The ImmuneTech™ Total IgE System may only be run on the Luminex¹⁰⁰™ Integrated System.

Indications for Use: The ImmuneTech™ Total IgE System is a quantitative *in vitro* diagnostic test system used as an aid in the clinical diagnosis of IgE mediated allergic disorders.

Substantial Equivalence Claim to:

MyAllergyTest™ System	K020387	4/17/2002
Pharmacia CAP System IgE FEIA	K991945	7/28/1999

Brief Description of Performance Data:

Studies were performed to evaluate the performance (method comparison, sensitivity, specificity, accuracy (recovery) and precision of the ImmuneTech™ Total IgE System.

Study	Result
Method Comparison	Correlation Coefficient 0.97; $y=1.00x+6.03$
Sensitivity	2 IU/mL
Specificity	Non cross reactive to IgG, IgA or IgM
Recovery	99.8%
Between Day Precision	CV 3-10 %
Within Day Precision	CV 2-9%

Expected results study indicate 76% of non-atopic individuals with total IgE levels < 25IU/mL and 89% of atopic individuals with total IgE levels of >100 IU/mL.

Conclusion: These studies demonstrate the substantial equivalence of the ImmuneTech™ Total IgE System to a currently marketed device that has been reviewed and cleared through the 510(k) notification process. They further demonstrate the suitability for use of the product for clinical laboratory professional use.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 19 2003

Ms. Vivianne Noetzel
ImmuneTech Corporation
P.O. Box 9433
17394 Via Del Bravo
Rancho Santa Fe, CA 92067

Re: k032251
Trade/Device Name: ImmuneTech™ Total IgE System
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobins A, G, M, D, and E Immunological Test System
Regulatory Class: Class II
Product Code: DGC
Dated: November 21, 2003
Received: December 2, 2003

Dear Ms. Noetzel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

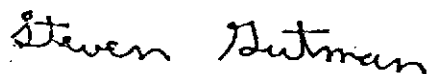
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K032251

Device Name: ImmuneTech™ Total IgE System

Indications for Use:

The ImmuneTech™ Total IgE System is a quantitative *in vitro* diagnostic test system that measures total IgE in human serum. The ImmuneTech™ Total IgE System is intended for clinical laboratory use. The ImmuneTech™ Total IgE System may only be run on the Luminex¹⁰⁰™ Integrated System.

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K032251

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDHR, office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-The-Counter Use _____